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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,195	11/20/2003	David C. Racenet	1879 CON III	9798
7590 08/05/2009 CHIEF PATENT COUNSEL TYCO HEALTHCARE GROUP 195 MCDERMOTT ROAD NORTH HAVEN, CT 06473				
EXAMINER NGUYEN, CAMTU TRAN				
ART UNIT		PAPER NUMBER		
3772				
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08/05/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/718,195

**Applicant(s)**

RACENET ET AL.

**Examiner**

Camtu T. Nguyen

**Art Unit**

3772

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 5-9, 11, 13, 17 and 20-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-9, 11, 13, 17 and 20-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11-20-2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 7/13/2009 has been entered.

Claims 5 & 13 have been amended. Claims 21-31 are newly added.

The Objections & the 112, 1st paragraph rejection have been withdrawn in view of applicant's amendment & remarks.

Applicant's remarks against the Molleneur reference as acknowledged, in particular, the Mollenauer do not teach seal member disposed in a housing (newly added), and thus, the rejection associated with such reference has been withdrawn.

Applicant's remarks against the Stephens et al reference are acknowledged, in particular, the Stephen et al do not teach two rings (newly added), and thus, the rejection associated with such reference has been withdrawn.

Applicant amended claim 5 to now recite a ring assembly including a first ring and a second ring, and the seal member is positioned between the rings. Applicant remarked that the Stephens et al reference do not discloses such element.

The claims, as amended, have been carefully considered but deemed not allowable in view of the following interpretation.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 20 recites the sealing member is non-inflatable.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “hourglass” shaped seal member embodiment having fabric & ring assembly must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 21, and 23-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claims 5 and 21, the disclosure specification does not have support for the sealing member positioned between the first ring & the second ring associating with the "hourglass" shaped seal member. Paragraph 0037 in the specification discloses ring members (120, 122) are snap fitted together on either side of seal member (118), referring to Figure 2. Accordingly, the embodiment Figures 11-13 illustrating the "hourglass" shape sealing member and these figures do not show the rings on either side or "sandwiching" the sealing member (218).

Regarding claims 23-27, the disclosure specification does not have support for the attachment structures associating with “hourglass” shaped seal member. Accordingly, paragraph 0037 in the specification discloses the attachment structures (120a, 120b, 122a, 122b) are snap fitting the ringer members (120, 122) together surrounding seal member (118), referring to Figure 2. Accordingly, the embodiment Figures 11-13 illustrating the “hourglass” shape sealing member and these figures do not show the attachments structures.

Regarding claim 28-30, the disclosure specification does not have support for the dampening element associating with “hourglass” shaped seal member. Accordingly, the dampening element is directed to the seal member (118) embodiment of Figure 2 and not with the seal member (218) embodiment of Figures 11-13.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 recites the limitation "the instrument" in line 10. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-9, 20-22, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young (U.S. Patent No. 5,391,154) in view of Stablein (DE 37 37 121 A1).

Young discloses in Figure 2 a cannula assembly (10) comprising a housing (10), a seal member (30) in hourglass shape (column 4 lines 57-63) disposed in the housing (10), the seal member (30) defining an opening (40) to receiving an instrument therein, the seal member (30) is resilient (column 4 lines 66-68, column 5 lines 1-8, column 6 lines 51-62) to accommodate & to provide a fluid seal with instrument(s) of varying diameter. Figure 3 illustrates a cannula member (24) extending across the seal member (30) and having a bore therethrough. Figures 2 & 4 illustrate a retaining assembly including a first retainer (48, 56) and a second retainer (50, 58), with the seal member (30) positioned between the retainers (56, 58) engaging each other to inhibit relative movement therebetween.

The Young seal member (30) does not comprising a fabric.

Stablein further discloses a sealing system for catheter/instrument insertion assembly, the sealing sleeve (2) is made of soft and flexible but tear-resistant material (natural or synthetic or soft plastic) and a fabric material is used to reinforce sealing sleeve (2), see last paragraph of column 2.

Therefore, it would have been obvious to one skilled in the art to modify the material of the Young seal member (30) such that it comprising a layer of fabric, as taught by Stablein, as such would provide not only flexibility during insertion of the instrument but also greater resistance, thus, to form a tighter fluidic seal in relation about the instrument.

Regarding claim 5 specifically reciting first ring and the second ring, with the seal member positioned there between, the rings are for purposes of inhibiting relative movement

therebetween, the Young retaining assembly (56, 58) perform the function as recited in claim 5, the Young retaining assembly (56, 58) is not excluded by any explicit definition provided in the specification for an equivalent. Therefore, it would have been obvious to one skilled in the art to substitute applicant's rings for Young's retainers (56, 58) as such would be more suitable with assembly in the Young device. Furthermore, one skilled in the art would have recognized Young's retaining assembly (56, 58) as one of equivalent to applicant's ring assembly.

Regarding claim 6 & 7, the Young reference teaches the seal member (30) is fabricated from an elastomeric material such as synthetic/natural rubber, which is resilient (column 7 lines 66-68).

Regarding claims 8 & 9, the Stablein reference teaches the sealing sleeve (2) is made of soft and flexible but tear-resistant material (natural or synthetic or soft plastic) and a fabric material is used to reinforce sealing sleeve (2), see last paragraph of column 2. One skilled in the art would conclude that the reinforcement would entails the sleeve/sealing member is integral with the fabric by disposing the sleeve/sealing member within the interstices of the fabric.

Regarding claim 20, the Young seal member (30) is non-inflatable.

Regarding claim 21, Figure 2 in the Young reference discloses the retainers (56, 58) are fitted snugly in recesses (52, 54), thus, the yielding the retainers (56, 58) would engage in a snap-fit relation.

Regarding claim 22, Figure 4 illustrates the first retainer (56) adjacent seal member's distal face and the second retainer (58) adjacent seal member's proximal face.

Regarding claim 31, the Young retaining assembly (56, 58) are formed of rigidity material.



Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Young (U.S. Patent No. 5,391,154)/Stablein (DE 37 37 121 A1), presented above, and further in view of Stephens et al (U.S. Patent No. 5,350,364).

Young/Stablein a cannula assembly (10) comprising all of the elements presented in these claims, as represented above, but does not teach the assembly (10) further comprising a zero seal in the housing.

Stephens et al discloses a trocar assembly (10) comprising flapper valve (164).

Therefore, it would have been obvious to one skilled in the art to modify the Young/Stablein cannula assembly (10) to include a flapper valve (164), taught by Stephens as such would substantially inhibit escape of insufflation gases absent of an instrument.

Claims 11 & 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young (U.S. Patent No. 5,391,154)/Stablein (DE 37 37 121 A1), presented above, and further in view of Hu (U.S. Patent No. 5,463,010).

Young/Stablein a cannula assembly (10) comprising all of the elements presented in these claims, as represented above, but does not teach the seal member (30) to include a coating of material for reducing friction between the seal member and an instrument inserted through the seal member.

Hu discloses and teaches the hydrocyclosiloxane membrane, a coating material for reducing friction between the seal member and the instrument used through the seal member.

Therefore, it would have been obvious to one of ordinary skill in the art to have a coating material applied onto the Young/Stablein's sealing member, as taught by Hu, as such would not

only protect biomedical device but also provide lubrication when the instrument is inserted through seal member.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/  
Examiner, Art Unit 3772

/Patricia Bianco/  
Supervisory Patent Examiner, Art Unit 3772